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Amendment No. 1 to SB3660

Herron
Signature of Sponsor

AMEND Senate Bill No. 3660* House Bill No. 3560

by deleting all language following the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, is amended to add an additional part to read as follows:

63-10-501. It is the purpose of this part to:

(1) Improve the health of needy Tennesseans through a prescription drug redispensing program that authorizes charitable clinic pharmacies to redispense medicines that would otherwise be destroyed; and

(2) Reaffirm the existing broad latitude of the Tennessee board of pharmacy to protect the safety of the prescription drug supply in this state.

63-10-502. As used in this part, unless context otherwise requires:

(1) "Charitable clinic" means a charitable nonprofit corporation or a facility organized as a not-for-profit corporation under title 48 that:

(A) Holds a valid exemption from federal income taxation issued pursuant to the Internal Revenue Code, 26 U.S.C. § 501(a);

(B) Is listed as an exempt organization under the Internal Revenue Code, 26 U.S.C. § 501(c)(3);

(C) Provides advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health on an outpatient basis for a period of less than twenty-four (24) consecutive hours to persons not residing or confined at the facility;

(D) May charge an administrative fee or request a donation not to exceed ten dollars ($10.00) per visit; and

(E) Has an outpatient pharmacy licensed by the board of pharmacy;

(2) "Charitable clinic pharmacy" means a pharmacy practice site licensed by the board of pharmacy where prescriptions are dispensed free of charge by a pharmacist licensed by the board of pharmacy to indigent patients that have been appropriately screened and qualified by the charitable clinic;

(3) "Controlled substances" means substances defined by § 63-10-204;

(4) “Donor patient” means a patient, or the patient’s representative in the event the patient is deceased or is not competent, who is the owner of the prescription drug and entitled to donate the drug for use by a charitable clinic pharmacy through an institutional facility;

(5) "Indigent" means a person with an income that is below two hundred percent (200%) of the federal poverty level;

(6) “Institutional facility” means a hospital, nursing home, home care organization, residential HIV supportive living facility, or residential hospice facility as defined by §68-11-201;

(7)

(A) "Prescription drug" means a drug defined by §63-10-204.

(B) "Prescription drug," for purposes of this part, does not include controlled substances; and

(8) "Properly transferred” means the storage, handling, and distribution of the drug under this part in:

(A) Accordance with the label; and

(B) Its dispensed, sealed, tamper-evident single user unit.

63-10-503.

(a) The prescription drug redispensing program established by this part shall be a pilot program to determine the efficacy of redispensing prescription drugs to indigent patients.

(b) The board of pharmacy, in cooperation with the department of health, shall develop and implement this pilot program consistent with public health and

safety through which unused prescription medications other than controlled substances may be transferred from an institutional facility to a charitable clinic pharmacy for the purpose of distributing the medication to Tennessee residents who are indigent.

(c) The board of pharmacy, in cooperation with the department of health, shall monitor the pilot program and submit two (2) reports along with any recommendations or findings to the health committees of the general assembly:

(1) The first report on or before March 1, 2007; and

(2) The second report on or before January 1, 2008.

(d) Participation in this pilot program by any individuals or entities including charitable clinics, charitable clinic pharmacies, drug manufacturers or institutional facilities shall be voluntary.

63-10-504.

(a) A charitable clinic pharmacy may accept for redispensing prescription drugs obtained from an institutional facility by the clinic pharmacy for relabeling and dispensing free of charge to an indigent patient pursuant to a valid prescription order.

(b)

(1)

(A)

(i) Any institutional facility participating in the drug redispensing program established pursuant to this part shall enter into a contract with a charitable clinic pharmacy for the transfer of drugs pursuant to this section.

(ii) No institutional facility may transfer drugs to any charitable clinic pharmacy pursuant to this section without entering into a contract as provided in subdivision (i).

(B) A contract entered into pursuant to subdivision (b)(1)(A) shall be approved by the board of pharmacy, in cooperation with the department of health.

(2)

(A) A contract entered into under subdivision (b)(1)(A) shall set out procedures for ensuring a safe chain of custody to protect the safety of all transferred drugs.

(B) The contract may specify that the charitable clinic pharmacy will either:

(i) Define a specified set of drugs that will be transferred from the institutional facility to the charitable clinic pharmacy;

(ii) Request from time to time the transfer of particular drugs;

(iii) Receive all the drugs that the institutional facility is authorized to transfer pursuant to this section; or

(iv) Make such other provisions as may be approved by the board of pharmacy.

(3) The pharmacist in charge at the charitable clinic shall be responsible for determining the description of the drugs that will be included in the contract.

(c) Donations of prescription drugs to a charitable clinic pharmacy shall meet the following requirements:

(1) The charitable clinic pharmacy accepts the drugs only in their dispensed, sealed and tamper-evident packaging which includes but is not limited to single-unit doses or blister packs with the outside packaging opened if the single-unit dose packaging remains intact;

(2) A pharmacist of the charitable clinic pharmacy determines that the drug is not adulterated or misbranded and is safe to dispense;

(3) No product of which the integrity cannot be assured is accepted for redispensing by the pharmacist of the charitable clinic pharmacy;

(4) The drugs are physically transferred from the institutional facility to a charitable clinic pharmacy by a person authorized by the state board of pharmacy to pick up the drugs for the charitable clinic pharmacy;

(5)

(A) The donor patient executes a form stating that the donor is authorized to donate the drugs and intends to voluntarily donate them to a charitable clinic pharmacy;

(B) The institutional facility retains the donor form along with other acquisition records;

(6) The donor patient’s name, prescription number, and any other identifying marks are obliterated from the packaging before the institutional facility sends the drug to the charitable clinic pharmacy;

(7) The drug name, strength, and expiration date remain on the drug package label;

(8) The redispensed drug is assigned the same expiration date as on the original package;

(9) Expired drugs accepted by a charitable clinic pharmacy are not redispensed and are destroyed according to the charitable clinic pharmacy's destruction procedures; and

(10) The charitable clinic pharmacy accepts no controlled substances.

(d)

(1) If an institutional facility that releases drugs to a charitable clinic pharmacy receives notice from another pharmacy that a drug has been recalled, the institutional facility shall inform the charitable clinic pharmacy of the recall.

(2) If a charitable clinic pharmacy receives a recall notification from an institutional facility, the charitable clinic pharmacy shall perform a uniform destruction of all of the recalled drug in the charitable clinic pharmacy.

(e) No drug dispensed through a charitable clinic pharmacy shall be eligible for reimbursement from the state Medicaid program.

(f) Indigent patients receiving prescription drugs through this program shall sign a waiver form releasing the institutional facility, the donor patient, and the donor patient's estate from liability.

(g) The board shall promulgate rules to develop:

(1) Forms and procedures for authorizations and certifications required under subdivision (c)(4);

(2) The donor consent form required under subdivision (c)(5);

(3) The waiver forms required under subsection (f); and

(4)

(A) Specific requirements for a charitable clinic pharmacy or other specialty pharmacy for the medically indigent as defined by rules of the board of pharmacy to qualify for participation in and to participate in the pilot program.

(B) On request, the board shall provide the information required under subdivision (g)(4)(A) to charitable clinics.

(h)

(1) The following persons and entities that participate in the pilot program shall not be subject to any criminal prosecution for actions taken under the program:

(A) The donor patient and the donor patient's estate;

(B) An institutional facility;

(C) The prescribing physician, physician's assistant, registered nurse, advanced practice nurse, or nurse practitioner;

(D) The charitable clinic;

(E) The charitable clinic pharmacy acting in conformity with board of pharmacy regulations;

(F) Pharmacists and pharmacy technicians acting in conformity with the board of pharmacy regulations issued pursuant to this part;

(G) The department of health; or

(H) The board of pharmacy.

(2) Participation in the pilot program shall not be used as an independent basis for a claim of liability in tort or other civil action against any person or entity, including, but not limited to:

(A) The donor patient and the donor patient's estate;

(B) An institutional facility;

(C) The prescribing physician, physician's assistant, nurse practitioner, or nurse;

(D) The charitable clinic;

(E) The charitable clinic pharmacy acting in conformity with board of pharmacy regulations;

(F) Pharmacists and pharmacy technicians acting in conformity with the board of pharmacy regulations issued pursuant to this part;

(G) The department of health; or

(H) The board of pharmacy.

(3) The following persons and entities that participate in the pilot program shall not be subject to any professional disciplinary action for action taken pursuant to this program:

(A) The donor patient or the donor patient’s estate;

(B) An institutional facility;

(C) The prescribing physician, physician's assistant, nurse practitioner, or nurse;

(D) The charitable clinic;

(E) The charitable clinic pharmacy acting in conformity with board of pharmacy regulations;

(F) Pharmacists and pharmacy technicians acting in conformity with board of pharmacy regulations;

(G) The department of health; or

(H) The board of pharmacy.

(4) In the absence of bad faith, a drug manufacturer shall not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by a donor patient pursuant to the pilot program, including, but not limited to liability for failure to provide:

(A) Product or consumer package insert information; or

(B) The expiration date of the donated drug.

Subdivision (4)(A) does not apply to a previously undisclosed product defect.

63-10-505. Nothing in this part shall restrict the use of samples by a physician or advanced practice nurse during the course of working at a charitable clinic whether or not the clinic has a licensed outpatient pharmacy.

63-10-506. Nothing in this part shall be construed to provide for the resale of drugs by any person or entity.

63-10-507. Nothing in this part applies to any questions of liability arising outside the scope of the pilot program.

SECTION 2. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 3. This act shall take effect July 1, 2006, the public welfare requiring it.